

REMARKS

Favorable reconsideration of the subject application is respectfully requested in view of the above amendments and the following remarks. Claims 1, 3, 4 and 27 are pending.

Specification

Applicants note the Action acknowledges the previously submitted amendments to the title of the specification.

Rejection Under 35 U.S.C. § 102(b)

Applicants thank the Examiner for withdrawing the previous rejection under 35 U.S.C. § 102(b) of claims 1 and 27, as allegedly being anticipated by Deng, *et al.*

Rejection Under 35 U.S.C. § 103(a)

Claims 1, 3, 4 and 27 stand rejected under 35 U.S.C. § 103(a) as allegedly rendered obvious in light of Deng *et al.* (Antimicrobial Agents and Chemotherapy, 1995), Marino *et al.* (Journal of Bacteriology, 1991), and Ohyama *et al.* (Journal of Bacteriology, 1992), and as allegedly evidenced in new reference Ronald (Handbook: Microbiological Media, 1997, CRC Press, Inc., Boca Raton, FL, pp. 1113, 1349, 1482, 1491, 1492).

The Action alleges that Deng *et al.* teach culturing *Mycobacterium smegmatis* in glycol-alanine salts medium in the presence of Tween 80 and a structure modifying compound, namely ethambutol, but concedes the reference does not disclose incubating the microorganism using 2,4-dinitrophenol (DNP) or carbonyl cyanide-m-chlorophenyl hydrazine. The Action further alleges Marino *et al.* teach incubating microorganisms in growth medium and 2,4-dinitrophenol (DNP), and alleges Ohyama *et al.* teach incubating microorganisms in growth medium in the presence of carbonyl cyanide-m-chlorophenyl. The Action alleges that Ronald teaches the use of detergents, such as Tween, in bacterial cell cultures is well known because Tween prevents clumping and may act as an energy source for some microorganisms.

Applicants respectfully traverse this rejection and maintain the Action fails to establish a *prima facie* case of obviousness. The Federal Circuit has held that a *prima facie* case of obviousness may only be satisfied by showing "some objective teaching in the prior art or that

knowledge generally available to one of ordinary skill in the art *would lead* that individual to combine the relevant teachings of the references.” (Emphasis original) *In re Fine*, 837 F.2d 1071, 5 U.S.P.Q.2d 1596, 1598 (Fed. Cir. 1988).

Applicants maintain the Action has merely identified some alleged elements of the invention in the cited references, but has not established any explicit or implicit reason, suggestion, or motivation to combine the elements of the cited references in order to arrive at the presently claimed invention.

Specifically, the Action alleges it is well known in the art that the use of Tween prevents clumping in high-density bacterial cultures, according to Ronald. Applicants submit one of skill in the art, if faced by the problem solved by the presently claimed invention, would not necessarily choose to add Tween, since testing for detection of bacteria is typically conducted with low levels of bacteria—not high-density bacterial cultures.

Applicants submit the present invention generally provides a novel, antigenic epitope exposing microorganism growth composition. *See* lines 8-9, page 5 of the instant Specification. In one embodiment of the present invention, microorganisms may be detected via visualization of interaction with internal antigenic epitopes that may ordinarily be inaccessible due to steric interference of outer surface antigens. *See* lines 13-23, page 4 of the instant Specification. Applicants further submit the novel compositions and methods claimed by the present invention allow for the unexpected advantage of detection of the presence of very low levels of microorganisms. *See* line 29, page 9—line 17, page 10 of the instant Specification. Such detection is only possible due to the combination disclosed in the presently claimed invention, one embodiment of which includes a general enrichment media, a detergent, and at least one structure modifying organic chemical, wherein the structure modifying organic chemical is selected from the group consisting of 2,4-dinitrophenol and carbonyl cyanide-m-chlorophenyl hydrazone.

Applicants submit one of skill in the art would *not* be motivated to include Tween in a low-density bacterial culture because cell clumping is scarce or non-existent. Applicants further submit neither Deng, *et al.*, nor Marino, *et al.*, nor Ohyama, *et al.* teach adding Tween to bacterial cultures, even though the cited references relate to studying various aspects of bacterial

growth. Thus, while one of skill in the art may use Tween for *some* bacterial cultures, the skilled artisan would *not* be motivated to use it if faced with the problem solved by the presently claimed invention.

The Federal Circuit has well-established that 35 U.S.C. § 103 specifically requires consideration of the claimed invention “as a whole,” and not part by part. *Envtl. Designs, Ltd. v. Union Oil Co.*, 713 F.2d 693, 698 (Fed. Cir. 1983) (noting that “virtually all [inventions] are combinations of old elements.”). The Federal Circuit has established assurance of an “as a whole” assessment of the invention under § 103 obviousness by requiring a showing that one of ordinary skill in the art at the time of the invention, confronted by the same problems as the inventor and with no knowledge of the claimed invention, would select the various elements from the cited references and combine them in the claimed manner. *Ruiz at 1275*, citing *In re Rouffet*, 149 F.3d 1350, 1355-56 (Fed. Cir. 1998). Applicants respectfully submit the Action is relying on hindsight in order to reduce the presently claimed invention to its parts, rather than considering the invention as a whole. Applicants further submit that the Action has failed to show any suggestion or motivation for one of skill in the art to combine specific elements that are allegedly taught in the references, to arrive at the presently claimed invention.

As an additional matter, Applicants submit the Action alleges “[t]he ordinary artisan would recognize that alteration of a bacterial cell wall would have an effect on the antigenicity of the cell.” See page 3 of the Office Action dated April 5, 2005. Applicants traverse this factual allegation as not being supported by documentary evidence. Applicants note that none of the cited references discusses the antigenicity of bacterial cell walls, and the Action provides no other documentary evidence for this allegation, yet relies on this allegation in order to render the claims of the invention obvious under 35 U.S.C. § 103(a).

Applicants submit it is not appropriate to take official notice of facts or rely solely on “common knowledge” in the art without evidentiary support in the record, as the principal evidence upon which a rejection is based. *In re Zurko*, 258 F.3d 1379, 1385, 59 U.S.P.Q.2d (Fed. Cir., 2001). Furthermore, it is only proper to take official notice of facts unsupported by documentary evidence where the facts asserted are “capable of such instant and unquestionable

demonstration” as to defy dispute. *In re Ahlert*, 424 F.2d 1088, 1091, 165 U.S.P.Q. 418, 420 (C.C.P.A. 1970).

Applicants traverse the Action’s allegation and submit that a finding that one of skill in the art “would recognize that alteration of a bacterial cell wall would have an effect on the antigenicity of the cell,” is not capable of instant and unquestionable demonstration of common knowledge in the art. Further to this point, Applicants submit the references cited herein utilize various bacterial cell wall structure modifying chemicals for purposes unrelated to the present invention, and at least one of the cited references discuss achieving “some type of cell wall change,” *See Deng, et al.*, 1st column, p. 694. However, none of the references discusses antigenicity of the bacterial cell.

Applicants respectfully request the Examiner “point to some concrete evidence in the record in support of these findings” that the ordinary artisan would recognize the alteration of a bacterial cell wall would have an effect on the antigenicity of the cell, in order to satisfy the substantial evidence test for the standard of review applied to findings of fact under the Administrative Procedure Act (APA). *See In re Gartside*, 203 F.3d 1305, 1315, 53 U.S.P.Q.2d 1769, 1775 (Fed. Cir. 2000).

Alternatively, if the Examiner is relying on personal knowledge to support the finding of what is known in the art, Applicants respectfully request an affidavit or declaration setting forth the specific factual statements and explanation to support the finding, in accordance with 37 C.F.R. 1.104(d)(2).

Applicants submit that even assuming *arguendo*, that the ordinary artisan would recognize that *any* alteration of a bacterial cell wall would have *any* effect on the antigenicity of the cell, such assertion would not provide a nexus to lead the skilled artisan to combine the elements selected from the references cited in the Action, in order to arrive at the presently claimed invention.

Applicants submit that one aspect of the present invention pertains to detecting microorganisms by way of antigenic epitopes that may ordinarily be inaccessible due to steric interference. Applicants assert that such finding is an unexpected advantage of the presently

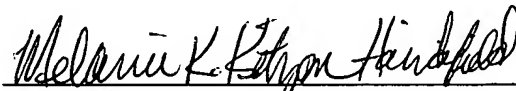
claimed invention *precisely because* one of skill in the art would not predict it. Thus, Applicants respectfully request this rejection be reconsidered and withdrawn.

The Director is authorized to charge any additional fees due by way of this Amendment, or credit any overpayment, to our Deposit Account No. 19-1090.

All of the claims remaining in the application are now clearly allowable. Favorable consideration and a Notice of Allowance are earnestly solicited.

Respectfully submitted,

SEED Intellectual Property Law Group PLLC

A handwritten signature in cursive script, reading "Melanie K. Kitzan Handfield", written over a horizontal line.

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